

§ 460.192

(v) Observation of program operations, including marketing, participant services, enrollment and disenrollment procedures, grievances, and appeals.

(2) A comprehensive assessment of an organization's fiscal soundness.

(3) A comprehensive assessment of the organization's capacity to furnish all PACE services to all participants.

(4) Any other elements that CMS or the State administering agency find necessary.

§ 460.192 Ongoing monitoring after trial period.

(a) At the conclusion of the trial period, CMS, in cooperation with the State administering agency, continues to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization's compliance with all of the requirements of this part.

(b) Reviews include an on-site visit at least every 2 years.

§ 460.194 Corrective action.

(a) A PACE organization must take action to correct deficiencies identified during reviews.

(b) CMS or the State administering agency monitors the effectiveness of corrective actions.

(c) Failure to correct deficiencies may result in sanctions or termination, as specified in subpart D of this part.

§ 460.196 Disclosure of review results.

(a) CMS and the State administering agency promptly report the results of reviews under §§ 460.190 and 460.192 to the PACE organization, along with any recommendations for changes to the organization's program.

(b) CMS and the State administering agency make the results of reviews available to the public upon request.

(c) The PACE organization must post a notice of the availability of the results of the most recent review and any plans of correction or responses related to the most recent review.

(d) The PACE organization must make the review results available for examination in a place readily accessible to participants.

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Subpart L—Data Collection, Record Maintenance, and Reporting

§ 460.200 Maintenance of records and reporting of data.

(a) *General rule.* A PACE organization must collect data, maintain records, and submit reports as required by CMS and the State administering agency.

(b) *Access to data and records.* A PACE organization must allow CMS and the State administering agency access to data and records including, but not limited to, the following:

- (1) Participant health outcomes data.
- (2) Financial books and records.
- (3) Medical records.
- (4) Personnel records.

(c) *Reporting.* A PACE organization must submit to CMS and the State administering agency all reports that CMS and the State administering agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates.

(d) *Safeguarding data and records.* A PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(e) *Confidentiality of health information.* A PACE organization must establish written policies and implement procedures to do the following:

(1) Safeguard the privacy of any information that identifies a particular participant. Information from, or copies of, records may be released only to authorized individuals. Original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas.

(2) Maintain complete records and relevant information in an accurate and timely manner.

(3) Grant each participant timely access, upon request, to review and copy his or her own medical records and to request amendments to those records.

(4) Abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, and other participant health information.